510(k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

The Assigned 510(k) number is k061005

Name of Submitter:
Applied DNA Technologies Inc.
3337 Fosca Street
Carlsbad, CA 92009
Tel.: (714) 624-2347
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OCT - 4 2006

Contact Person:
Feng-Yu Lee

Identification / Product Name:
ACCUSTEP Single and Multi-Strip Cassette/Dipstick DOA Screen Panels

Description:
One-step, colloidal gold based chromatographic immunoassay for the rapid, qualitative detection of Marijuana, Cocaine, Phencyclidine, Morphine, Methamphetamine, Methadone, Amphetamine, Barbiturates, Benzodiazepines and Nortriptyline, a Tricyclic Antidepressant, in human urine.

Intended Use:
The Applied DNA Technologies ACCUSTEP DOA Screen Panels are rapid chromatographic immunoassays for the qualitative and simultaneous detection of one to ten of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration
Amphetamine	**AMP**	**Amphetamine**	**1000 ng/ml**
Barbiturate	**BAR**	**Secobarbital**	**300 ng/ml**
Benzodiazepines	**BZO**	**Oxazepam**	**300 ng/ml**
Cocaine	**COC**	**Benzoylecgonine**	**300 ng/ml**
Marijuana	**THC**	**11-nor-Δ^9-THC9-COOH**	**50 ng/ml**
Methamphetamine	**MET**	**Methamphetamine**	**1000 ng/ml**
Methadone	**MTD**	**Methadone**	**300 ng/ml**
Morphine	**MOR**	**Morphine**	**2000 ng/ml**
Phencyclidine	**PCP**	**Phencyclidine**	**25 ng/ml**
Nortriptyline,	**NOR**	**Nortriptyline**	**1000 ng/ml**

These test kits are intended for health care professional use only.

This assay provided only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Predicate Kit:
ACON One Step Multi-Drug Screen Test Card are used as predicate device for ACCUSTEP Single and Multi-Strip DOA Screen Panels to compare their performance with the GC/MS confirmed clinical urine specimens.

510(k) number for these predicate devices are:
ACON One Step Multi-Drug and Multi-Line Screen Test Card and Device K023946
ACON One Step Multi-Drug and Multi-Line Screen Test Card and Device K020313

Performance:
The product performance characteristics of ACCUSTEP DOA Screen Panels were evaluated in the blind-labeled spiked control studies and in the blind-labeled clinical specimen correlation study. The results of these studies demonstrate the ACCUSTEP DOA Screen Panels to be substantially equivalent to the performance characteristics of GC/MS methodology as well as ACON's One Step Multi-Drug Test Panels. Correlation studies, using clinical specimens, produced a >92% correlation when compared to the GC/MS methodology.

ACCUSTEP DOA Screening Panels vs. GC/MS Analysis

Samples with drug concentration above the cutoff level were considered presumptive positive and concentration below the cutoff were considered negative.

Test	Positive Agreement	Negative Agreement	Overall Agreement
AMP	46/48 = 95.8%	55/55 = 100%	101/103 = 98.1%
BAR	45/46 = 97.8%	51/52 = 98.1 %	96/98 = 98.0%
BZO	41/43 = 95.3%	52/56 = 92.9%	93/99 = 93.9%
COC	55/56 = 98.2%	53/54 = 98.1%	108/110 = 98.2%
MET	61/63 = 96.8%	52/52 = 100%	113/115 = 98.3%
MOR	40/41 = 97.6%	63/64 = 98.4%	103/105 = 98.1%
MTD	49/51 = 96.1%	54/54 = 100%	103/105 = 98.1%
PCP	45/46 = 97.8%	48/48 = 100%	93/94 = 98.9%
NOR	35/38 = 92.1%	57/57 = 100%	92/95 = 96.8%
THC	60/62 = 96.8%	59/60 = 98.3%	119/122 = 97.5%

Conclusion:
Results of Accuracy, Sensitivity, Precision, Specificity and Interference studies demonstrate the substantial equivalency between the ACCUSTEP DOA Screen Panels and the ACON One Step Multi-Drug Screen Test Card. It is also demonstrated that ACCUSTEP DOA Screen Panels are safe and effective in detecting Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methamphetamine, Methadone, Morphine, Phencyclidine, and Nortriptyline, a Tricyclic Antidepressant, in human urine specimen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Feng-Yu Lee
Vice President of Operation
Applied DNA Technologies Inc.
26251 Verona Place
Mission Viejo, CA 92692

OCT - 4 2006

Re: k061005
Trade/Device Name: ACCUSTEP Single and Multi-Strip Cassette/Dipstick DOA Screen Panels
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, DIO, LDJ, DNK, DJC, DJR, LCM, LFG
Dated: August 4, 2006
Received: August 8, 2006

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061005

Device Name: **ACCUSTEP Single and Multi-Strip Cassette/Dipstick DOA Screen Panels**

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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